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Citation for published version:

Jeffery, R 2018, War against disease without violence to clinical trial participants? in S Chandra (ed.), *Violence and Non-Violence Across Time: History, Religion and Culture*. 1 edn, Routledge India, Abingdon; New York, pp. 222-246. <https://doi.org/10.4324/9780429466205>

Digital Object Identifier (DOI):

[10.4324/9780429466205](https://doi.org/10.4324/9780429466205)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Peer reviewed version

Published In:

Violence and Non-Violence Across Time

Publisher Rights Statement:

This is an Accepted Manuscript of a book chapter published by Routledge India in *Violence and Non-Violence across Time: History, Religion and Culture* on 26th June 2018, available online: <https://www.routledge.com/Violence-and-Non-Violence-across-Time-History-Religion-and-Culture/Chandra/p/book/9781138203297>

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War against disease without violence to clinical trial participants?

Roger Jeffery

‘War’ discourses characterise increasing areas of modern life, from the wars on illegal drugs, on terrorism, on racism and on illegal immigration, and wars on disease are also commonplace. Other martial metaphors include the use of patients as ‘targets’ or seeing pharmaceuticals as ‘golden bullets’ in the treatment of disease. In India since 2005, this kind of approach and its implications for the management of clinical trials of potential new drugs has raised serious concerns amongst regulators, parliamentarians, and civil society organisations. Clinical trials raise some thorny ethical issues everywhere, more problematically in highly inegalitarian societies like India that are rapidly developing. Sometimes the ‘ends’ for which the trial is being carried out are challenged; more often, the ‘means’ by which trials are achieved are accused of putting trial participants at unwarranted risks. Taking ‘informed consent’ from trial participants may neither inform nor ensure voluntary consent, but rather becomes a way of protecting researchers. Responsibility for ‘serious adverse events’ (including death) affecting those on a trial is often distributed and avoided by all stake-holders. Continuity of care – in trials involving chronic illnesses – is rarely provided, so that patients whose lives have been eased by new treatments may find them suddenly unavailable except at high cost. This chapter asks if the concepts of ‘structural violence’ (with its associated notion of ‘structural coercion’) or approaches drawing on Bourdieu’s concept of ‘symbolic violence’ offer a useful handle on such events.

Introduction

In 2006, the Bill and Melinda Gates Foundation granted PATH, a Seattle-based NGO, US \$27.8 million to conduct research in India, Peru, Uganda, and Vietnam ‘to gather the evidence countries need to make informed decisions about how to introduce a vaccine’ against two types of Human Papilloma Virus (HPV), which is a precursor to some kinds of cervical cancer (see also (McCoy et al. 2009)).¹ In partnership with the Indian Council of Medical Research (ICMR), PATH carried out post-licensure observational studies in two Indian States, Andhra Pradesh and Gujarat. No biomedical outcomes were researched; no blood or other samples were drawn; and no new therapies were tested. The safety and efficacy of these vaccines had already been assessed in many clinical trials and endorsed by international and national regulatory agencies. PATH and the ICMR took ethical clearance in India and the USA, and involved the governments of the two States in delivery of the vaccine to selected groups of adolescent girls. Starting in 2009, they vaccinated over 23,000 girls. Despite all these precautions, in 2010, after a huge media outcry, the studies were suspended. Protests spiralled, and enquiries were instigated by the Indian Parliament and its Supreme Court.

The Supreme Court responded to a Public Interest Litigation petition filed in February 2012, which sought to halt the conduct of all clinical trials in India for new products. It alleged that weak regulatory controls on the conduct of clinical trials, combined with their poor enforcement, had contributed to an unacceptable number of deaths – estimated at 2,262 clinical trial participants in 2006–11 – and other adverse events. Furthermore, many trials were for drugs and devices that would not be sold or marketed in India, and would thus not advance Indian healthcare. In an internationally unprecedented interim ruling on 30 September 2013, the Supreme Court of India halted the approval by the Drugs Controller General-India (DGCI) of new clinical trials, pending a more effective review and monitoring system. Reports by a

joint committee of the two Indian houses of Parliament also reviewed the PATH trial, and the operations of the regulatory body, the Central Drugs Standards Control Organisation (CDSCO), making sweeping criticisms (Parliament of India 2012; Parliament of India 2013).

This chapter considers the utility of concepts of violence and non-violence in understanding how such apparently safe and desirable health interventions, initiated with benign intent, could have become the cause of so much ferment. After briefly discussing the introduction of the assemblages that constitute clinical trials globally in the 21st century (including the origins and key features of the ethical codes drawn upon in assessing and approving them), I present some examples of the main problems that have arisen in India. I then turn to a critical discussion of the dominant approaches to the human rights challenges that these Indian clinical trials exemplify, through the lens of ‘structural violence,’ in non-Marxist and Marxist variants and then Bourdieu’s concept of symbolic violence. In conclusion, I will assess the utility of these approaches not only for understanding the key problems but also for assessing public policy to mitigate them.

Global Ethics, Global Trials

Bio-medicine – the versions of medical practice with their origins and bases predominantly within Europe, North America and Japan, or the Global North – has been transformed since the end of the Second World War. Nowhere is this more obvious than in how new medicines are assessed and introduced into the ‘armoury’ which doctors can access. The organised, systematic collection of data on a large scale about the uses and dangers of potential medicines, barely visible before the 1950s, now operates on a global scale. Ethical codes to prevent human rights abuses were developed in response to the horrifying evidence of how camp doctors in Nazi Germany coerced inmates into dangerous, painful and often deadly experiments. Legal frameworks, medical and para-medical training programmes, and the activities of medical associations now embody these codes.

Fischer (2006) usefully lists the history of the development of the Nuremberg Code, the World Medical Association's Helsinki Declarations, and the Good Clinical Practice (GCP) guidelines of the International Conference on Harmonisation (ICH). The ICH-GCP guidelines have come to dominate international trials; they focus on procedures, whereas the Helsinki Declarations include a concern with moral principles (Goldacre 2012: 118-119). For example, the Helsinki Declaration states that research must benefit the population within which it is being trialled, whereas the ICH-GCP is silent on this point. One aspect of this potential benefit – the post-trial availability of medicines – is a salient issue if the trial is successful, chronic illnesses are involved, and (as in India) there is no effective National Health Service. In one study, nearly half of the successful drugs trialled in 2010 were not licensed for sale in India (Limaye et al. 2015: 2-4).

For India, the ICMR produced “Ethical Guidelines for Biomedical Research on Human Participants” in 2006, reflecting most international standards but specifying more protection of vulnerable populations and minorities, the compulsory registration of all new clinical trials in the Clinical Trials Registry of India (from 2009) and the registration of ethics committees (Burt et al. 2014). Yet the enforcement mechanisms are opaque, and the ICMR itself breached its own regulations as a co-sponsor of the PATH study.

How to provide a moral compass for trial managers has become the subject of intense debates amongst ethicists and medical personnel, who have offered various solutions to the main concerns surrounding medical experiments: with informed consent; with the choice and control of interventions (whether, for example, to use a placebo or current best practice); with whether special procedures are necessary for ‘vulnerable’ sub-groups of a population such as children; and with the scale and form of compensation for any adverse events that result from involvement in a trial.

Only some ‘clinical trials’ offer suffering patients the opportunity to try out new – and potentially life-saving – drugs, or vaccines that might protect them from life-threatening diseases.² Drug or vaccine researches might now start with computer simulations of molecules and their likely effects followed by tests on animals, before reaching Phase I – sometimes called ‘first in human’ – trials on healthy volunteers. Phase II trials expand the trial to a larger group of patients with the relevant condition, to test dose levels, efficacy and side-effects. Phase III trials, increasingly double-blind, randomised control trials on many patients, in multiple sites, offer the drugs to patients with the disease in question. ‘Double-blind’ trials are ones in which neither the patients nor those treating them know if they are receiving the drug being tested or an alternative, an inert substance – a placebo – or one or more versions of current good practice. Patients are recruited according to very specific rules, set out in the trial protocol, which is set by the sponsor of the trial, usually a large pharmaceuticals company based in north America, Europa or Japan (Sariola et al. 2015).

These global assemblages of clinical trials involve expectations of, and aspirations to, universal standards of design, method, reliability, validity, and reporting of results – as well as of ethical procedures. The sponsors try to impose their own protocols, rules and guidelines, but inevitably lose a degree of oversight as they negotiate with local partners for trial approval, recruitment of patients etc. The local teams co-construct – from very unequal starting points – the practicalities of any particular research project. Local ‘principal investigators’ are responsible for communicating the risks and hazards that feature prominently as part of these processes. But once trial sponsorship and management is out-sourced in this way, responsibilities are hard to pin down (Glickman et al. 2009). For example, in the Oasis-6 cardiac trials in Bhopal, discussed below, a French company developed the drug, a British one sponsored the trial, and an Indian CRO managed the trial in India; the trial co-ordinator was based in Canada (Lakhani 2011).

Clinical trial assemblages are the ‘cutting edge’ in a process of de-territorialisation which bring global procedures into everyday settings [hospitals, laboratories etc.] and attempt to render them coeval and continuous with others around the globe. Furthermore, clinical trials manage trial subjects and induct them into the global laboratory that such procedures represent. Trials are gatekeepers to a global modernity for members of these assemblages, who regulate access to different regimes of care but also to new temporalities [via the research process], new spaces [in the clinic/ hospital as laboratory], and most important, futures [as biological citizens (Rose and Novas 2005), biomedical citizens (Petryna 2005), therapeutic citizens (Nguyen 2005) pharmaceutical citizens (Ecks 2005) or bioethical citizens (Simpson et al. 2015)].

The ethical issues (or the kind of ‘violence’) vary between phase I (small numbers of healthy volunteers) and phase III (large numbers of sick people). But the context within which the trials take place also matters. Between the 1990s and the 2010s, clinical trials activity has shifted significantly, to recruit participants from many countries beyond Europe and North America. Since 2005, India has been included as an option for ‘multi-sited global clinical trials’ that recruit participants from many different sites, often spread over many countries, in order to speed up recruitment and to reduce costs.

India in Global Trials

Until 2005 clinical trials could not be conducted in India in the same phase concurrently with trials elsewhere, leading to a ‘phase-lag. In 2005 the law governing clinical trials was amended to allow concurrent trials of drugs and devices with trial sites abroad, except for Phase I. Until 2011, Phase III trials were the most numerous in India (Borkar, Jacob and Ravindran 2011; Ravindran and Nikarge 2010); after that, the numbers of Phase I trials have matched those of Phase III. About half of these studies involved foreign sponsorship. Different sources give very different indicators of the proportion of globalised trials that include sites in India, but they

agree that from 2005 to 2010 the numbers grew rapidly, declining thereafter (Burt et al. 2014). In addition to the global multi-sited trials, leading Indian pharmaceuticals companies have increased the numbers of trials they carry out (Malhotra 2008). Nonetheless, India accounted for only a small proportion of all registered global multi-sited trials in the peak year.

As far as Indian doctors and business, clinical research organisations, hospitals and the Government of India's Department of Bio-Technology are concerned, however, clinical trials are rarely described as offering benefits to the Indian population in terms of access to new and better drugs (Bajpai 2013). Rather, global clinical trials represent a new set of financial and employment opportunities. The Indian trade press regularly repeats claims of the financial benefits to foreign innovator companies and contract research organisations of the large clinically-naïve population in India, the availability of high quality hospitals and researchers speaking good English, and the low costs – supposedly around half those for equivalent trials in the USA (Yee 2012: 397). Companies may also outsource trials in order to avoid the close surveillance of the FDA, EMA and other international agencies, which have much less information on trials conducted somewhere like India. This situation is changing, as these agencies demand more information about the standards being followed in outsourced trials. Authors based at the US FDA have produced a long list of the factors that need to be taken into account when designing multi-regional trials – highlighting the large differences between India and the main centres of such trials in North America, Western and Eastern Europe. Rather than acknowledge these differences, and find ways to adapt to local circumstances, however, FDA officials attempt to remove them: 'It is therefore critical to anticipate and decrease, to the extent possible, variability by using precise definitions, similar treatment standards, concomitant treatments, and so on' (Khin et al. 2013).

When global clinical trials arrived in India, the procedures for regulating them were slow to react. CDSCO and the state-level equivalents had too few staff to cope, and they were – in general – inadequately trained. In India, the number of staff in the state FDAs and in CDSCO are still far too few for their main tasks of regulating production and distribution of drugs, let alone taking on board assessing clinical trials (Kadam et al. 2016). To begin with, many of those involved in running and regulating clinical trials did not understand what they were ‘about’. In the industry’s self-representations, clinical trials are to discover, test and make available new treatments for existing and emerging threats to health. The reasons for the shift to India to conduct trials are often couched in these terms. Much is made of the need for faster recruitment, as well as the need for data that enables regional requirements to be met. For some diseases, epidemiology requires recruitment from specific regions. More commonly, industry sources stress issues of cost: ‘Locations such as India are attractive for these activities due to significantly lower costs and a good availability of qualified employees’. But these trials are also ‘about’ generating, if possible, massive profits for the companies that get there first, in any particular race, according to the logic of capitalist economies (Rajan 2012). They also help to open up a market for existing drugs in new markets, through brand recognition.

India became a new entrant in a highly differentiated, entrepreneurial environment, competing for business in the testing of molecules, most of which will not reach the market. Those that do are destined for those markets where the largest profits can be made – quintessentially the USA, but also Canada, Europe, Japan and Australasia. The overwhelming majority of drugs being tested are for chronic conditions common in these post-industrial societies, because these offer the highest potential returns to the sponsoring companies. Although some of these – for example diabetes, coronary heart disease or some cancers – also have growing numbers of Indian sufferers, Indians are not the main focus of this effort. Both globally and in terms of research carried out in India, research priorities follow a market logic.³ Once new drugs have

been approved and licensed for sale, sufferers in India need health insurance (which covers less than 10% of the Indian population), sufficient wealth, or to negotiate complex arrangements to get access to free or cheap drugs provided by the originator companies (Ecks 2010).

The shift of clinical trials into resource-poor settings raises several social, political and ethical issues, usefully summarised by a Nuffield Trust committee (Nuffield Council on Bioethics 2002). On the positive side, conducting trials in India and other developing countries should ensure that drugs are safe and effective for their populations, since there may be genetic variations that affect how the drug works. But on the down-side, there are many opportunities for human rights abuses. Should these activities in the globalised 'war against disease' be allowed in India if the drugs do not address the health needs of Indians, or become too expensive for them to access, or if the context of the trials inevitably recruits participants in questionable ways, in which no-one can be held responsible for what has been done to people? In the next section I discuss the Indian contexts within which these trials take place, and the features that have been identified as potential sources of coercion, whether direct or indirect, hidden or visible.

The Regulation of Clinical Trials in India

The main claims about why India is different – if not from the rest of the world, at least from those countries where clinical trials have developed furthest towards ethical standards being applied successfully – are as follows. Firstly, it is claimed that trials conducted in India do not face the same stringency in following the rules, so that the data are more likely to be distorted. Secondly, critics suggest that the social conditions, or the meaning-contexts, of trials – especially trials that involve poor, seriously ill patients – are so different from those envisaged by the rules that they cannot ensure that patient interests are protected. Thirdly, there are a series of claims about more technical issues, such as the conditions for informed consent in a

poorly educated and vulnerable population. Fourthly, people query whether it is ethical to test new drugs on a population when the drugs themselves, if approved, will not be available to them – or only at prices so high as to rule out any effective access. Other issues – such as compensation in cases where the treatment has adverse side-effects – have also been raised.

Distortion of data

The work of a CRO is largely a straightforward process of sending a Clinical Research Assistant or a field-worker to each research site and verifying that the data recorded for the trial actually reflects what happened to the patient enrolled in the trial. Well-known threats to the quality of the records include the invention of data; reporting successful treatment when a patient did not complete the course, or failed to improve; record irrelevant information; mislay specimens and forms; or fail to keep adequate records of informed consent. Internationally, there is a perception that Indian trials are more vulnerable to problems of this kind than in the USA, for example (Harris 2014). Good Clinical Practice, and its linked regulations, are not as well known as in countries with more experience. Some well-publicised pharmaceutical scandals have undermined the credibility of results from Indian companies (on Ranbaxy, see Eban 2013; on GVK Biosciences, see European Medicines Agency 2015), even though evidence to support this general presumption – that standards are not as closely followed in India as elsewhere – is hard to find and may be part of attempts by competitors to gain an unwarranted advantage. Many accounts suggest that US FDA monitoring provides reassurance that standards are being maintained (Editor 2000: 2177). Commentators often welcome the increase in its monitoring that followed the opening of its offices abroad (including in India and in China).

Clearly, all down the chain, throughout the assemblage, all those involved in running a trial have a vested interest in having their claims of rigour accepted. In September 2015, for

example, the Gujarat FDA called in German and French media for ‘assuaging the fear and confusion emanating from the European nations over the quality of the drugs that are manufactured in the country after the GVK fiasco’ (Anon. 2015). But these concerns are largely to do with *documentation* rather than with *process*. Any trial participant might wish to ensure that the documentation of their contributions are honestly, accurately and fully recorded, since otherwise their participation becomes worthless, as far as the trial is concerned, and they will have undertaken risks (of adverse events, of being given a placebo, or an untried and less effective new treatment) without even the feeling that others might benefit.

The social contexts of trials

There is little regular reporting of the social backgrounds of trial participants (Srinivasan 2009). In the civil society critiques, the focus is always on poor, marginalised participants, as in the PATH study of HPV vaccines. As far as Phase III and Phase IV trials are concerned, the most marginalised people are rarely involved, since they do not even reach the hospitals where the trials are conducted. They are more likely to be the ‘healthy volunteers’ needed for Phase I trials, since these are normally paid for their participation. As elsewhere, such participants often enrol in multiple trials, and the payments are a major incentive for people near the bottom of the social scale, as the few reports available suggest (see, for example, (Hundley 2008b). Although public hospitals take part in many Phase II and Phase III trials in the major Indian cities, when trials travel to smaller towns they are more likely to have co-investigators from private hospitals, whose patient populations are unlikely to include the poorest. Yet patients who are unable to pay the fees for the standard treatment may suddenly be offered free treatment, or even to be paid a fee, if they register for a clinical trial (Hundley 2008a). One ‘selling-point’ for India has been that many patients are ‘treatment-naïve’, i.e. have not already

been treated for the disease under investigation, suggesting a preference for those whose contact with the health system has been limited.

Evidence gained from detailed investigations show how far recruitment to some clinical trials in India has involved some of the most marginalised and vulnerable people. In Bhopal, from 2004–2012, they involved those left disabled by methyl isocyanate (MIC) in the gas leak on the night of 2–3 December 1984. In the immediate aftermath of this leak, many aspects of the disaster were hidden – such as the actual chemical that was released. The inadequacies of the local health services were brutally exposed, both in their lamentable responses to the acute needs of those who had been poisoned, and in their failure to provide appropriate care for the chronic illnesses of those exposed to the gas, and of their children. Over the following years, official and private responses were uncoordinated and provided only under considerable pressure from NGOs and advocacy groups. Patient record-keeping practices made it difficult if not impossible to be sure that survivors' needs were being taken into account: in Government hospitals it was impossible to follow the care of an individual patient, and in private facilities, records were given to the patients (Eckerman 2001). The Bhopal Memorial Hospital and Research Centre (BMHRC), established in August 2004, was supposed to concern itself exclusively with the treatment of gas victims and their families and to carry out research on the long-term effects of MIC exposure.

Yet soon after the BMHRC was opened, drug trials were conducted there for US and Indian companies, for various anti-bacterials and anti-coagulants. None, apparently, focused on the effects of the gas or took account of the existing multi-drug therapy for treatment of MIC-related ailments. Only six trials were fully reported to the CDSCO. There were 14 deaths, ten of whom were gas victims. Investigations into these deaths were cursory, and no compensation has been paid out. The hospital's Institutional Review Board (IRB) included staff from within

the hospital that had direct financial interests in the clinical studies being conducted. Given that the hospital is said to have received about \$200,000 in fees for these studies, conflicts of interest were inevitable. Ethical review before approval was brief and superficial, and informed consent was not taken from many of the participants; doctors themselves signed off on the consent forms. Questions about all these issues have been left unanswered. The existence of trials like this, even if they are uncommon, raises 'questions about the regulation and approval process for the testing, besides bringing the quality of research in India under a cloud' (Krishnan 2012; Lakhani 2011; Varma 2011).

Informed consent in poorly educated and marginalised populations

A major focus of concern has been the adequacy of ethical review procedures in situations where the social distance between potential trial participants and trial investigators is wide, leading to the possibility of abuse of power and privilege to coerce individuals into trials. The idea of a placebo, or even that patients may not be receiving their doctor's preferred treatment, may be hard to convey. Financial compensation for taking part may be so substantial that it becomes an overwhelming inducement.

Most Indian clinical trial participants have difficulty to understand what is involved when they sign up. They cannot easily recall key features of the trial; the recruiter often frames this information with a positive spin, giving little attention to the right to withdraw or about alternative therapies; and the delivery of the right amount of information – pitched at a level that aids comprehension – is rarely achieved (Siminoff, Caputo and Burant 2004). Examples abound. Here is a case in which a man with terminal cancer was enrolled in a trial involving head shaving (or not) before his brain surgery:

... the consent forms Iqbal signed on his father's behalf were in English, a language he neither speaks nor reads. "If they had been in Bengali, I could have followed them," he said ... (T)he trial had nothing to do with chemo or radiation. It simply tracked the infection rate in patients whose heads were not shaved before brain surgery. ... "The doctor told me shaving heads was the old process, that not shaving is the latest," he said as the sunlight faded. "I just told the doctor, 'Do what is good. You are god to me' (Hundley 2008b).

If the language of the researchers is different from the home language by the participants, the need to 'explain the consent form in simple language to the participants' is made more difficult (Bhansali et al. 2009); see also (Joglekar et al. 2013). Problems of 'therapeutic misconception' – the mistaken belief that entry into a trial will ensure better treatment for the underlying disease – are common in almost all settings, not just in India. But the risk of therapeutic misconception is considerably enhanced in the absence of effective national health systems. Such misconceptions persist despite what appears to be an adequate informed consent process. In countries like India, to carry out trials where the alternative to enrolment is not 'current best practice' but 'no treatment at all' or 'treatment that might be so expensive as to push participants into (even more acute) poverty' is not ethical, but can be considered the result of various forms of violence, as I discuss further below.

In practice, most research protocols in India are drafted in English, and then translated (who does this job is not usually revealed, nor if or how they are tested for comprehensibility) and many documents remain in English. Rajan describes a company that he terms 'gold-standard' with a deep and sincere commitment to good clinical practice, one that requires its trial participants to be literate, though not in English. Yet the bulletin board in the waiting room

with information about the risks involved in taking part in a Phase I trial included only documents entirely in English (Rajan 2007: 76-77).

For a significant minority – in many studies involving Indian participants – information is seen as irrelevant, however, because willingness to take part depends on the ‘faith’ or ‘trust’ in a medical practitioner. As one interviewee in a north Indian study put it, ‘We’ll only take the new agent because doctors are telling us to. If they tell us to take a particular medicine, we will surely do so even if it is poisonous’ (DeCosta et al. 2004).

Some Indian studies suggest that, with care and attention to the translation of documents, to the setting within which consent is taken, and to the use of paramedical or other staff rather than doctors to transmit the information, reasonably good levels of understanding can be achieved even in marginalised groups (Joglekar et al. 2013). But even so, the context is radically different from that in which informed consent has been developed as a technology:

In this part of the world, the potential subject is from a family and community oriented culture, his/her normal decision making process involves his/her reference group, and exclusion of that group from that process damages the process. Related to this is the point that patients from cultures which value or expect paternalism, and place a high degree of systematic trust and reliance in the doctor’s expertise, need to have this respected in the consent process (DeCosta et al. 2004).

Ethical Review Committees

Ethical Review Committees (ERCs) should have as one of their key tasks to prevent any coercion – whether structural or symbolic – in the recruitment of participants to clinical trials. In practice, membership of ERCs involves long hours, exacting work, an unfeasible workload and the threat of hostility from researchers upset by unfavourable decisions (Simpson et al.

2015). Many members display enthusiasm when talking about the value of ethical review, and are aware of the possibility that, as a Professor of Medical Ethics in the UK describes it, 'they will be merely a moral fig-leaf covering ... structural violence' (Ashcroft 2005). They accept that their work is a small response in the face of a much bigger problem, because of the pressures to review several trials in a short period of time, with limited training, little or no administrative assistance and no chance to verify whether the trials they approve actually follow the procedures as promised. 'Lay' members working for 'institutional' review boards, set up by a hospital or medical college to review in-house research proposals, may be selected for their pliability; the medical members are vulnerable to pressures from colleagues. Independent review committees may be purely commercial in orientation, offering light-touch reviews. Sponsors faced with a rigorous review procedure may withdraw a proposal and submit it elsewhere, to an ERC where other priorities are important (Hundley 2008a). While some of these threats to good practice can be avoided, abuses could slip through the rather coarse net set up to hold them back. Since 2012, anecdotal evidence suggests that these committees are much more willing to delay the approval of trials when members are not satisfied that they are fully ethical. In this respect, they have become in some ways part of the response to reports of unethical practice.

Responses to Reports of Abuses

The case for an indignant response to the prospect of global clinical trials coming to India was made forcefully in 2005 by the editor of *Indian MIMS* and a colleague, calling them 'illegal and unethical' and characterising the situation as 'a new colonialism' (Nundy and Gulhati 2005). This moral position is not, however, universal. A CRO conducting trials within India justified his work on the grounds that it is time India 'pulled its weight' in what he sees, apparently, as a necessary evil, or at least morally problematic:

The time was when India was dependent on the western population being subject of clinical trials. I think we have derived enough medicine from there. I think the argument that we are being used as victims of clinical trials – even though you have to take extreme view on it – may not necessarily be true because it was happening for decades or centuries where people from the west have contributed some of the medicines that we are enjoying right now. So it's time we have to start contributing.

The PATH/ICMR study with which I began this chapter provides a coda to this argument. The 'informed consent' procedures were badly flawed. A substantial number of those included in the trial were girls from Adivasi backgrounds living in hostels, and extra care should have been taken beyond that appropriate to the protection of children in general. It is not clear why girls living in areas remote from good medical care were selected for the study, rather than a balanced spread across social and residential settings, as the internal review committee pointed out (Sarojini et al. 2010).

The 41-member Parliamentary panel ... says the implementation of the PATH study in both states was flawed. It says serious adverse events were not monitored and consent of trial subjects were not taken properly. For instance, many consent forms had only thumb impressions, most parents and guardians of the girls were illiterate and 69 out of 100 forms in Andhra Pradesh bore no signatures of witnesses, which was mandatory (Jayaraman 2013).

Of the approximately 24,000 girls aged 10–14 who received either Merck's Gardasil or GlaxoSmithKline's Cervarix vaccine seven girls — five in Andhra Pradesh and two in Gujarat — died within a year or so of receiving the vaccines. Only fragmentary evidence was available about the causes of these deaths. The official report into the PATH study identified 'clear

violations’ but no action was suggested, with ‘the committee exonerating all involved in the project’ (Sarojini et al. 2010): 19.

One of the defenders of the study expressed perhaps most clearly the lack of empathy between the sponsors of such trials and the people undergoing them. Dr Seth Berkley, chief executive of the GAVI Alliance, a public-private partnership that is ‘focused on saving children's lives and protecting people's health by increasing access to immunisation in poor countries’ wrote:

India has the largest number of cervical cancer deaths in the world. Suspension of the jab will inevitably cost lives. ... But perhaps the most compelling evidence is that the suicide rate for girls in southern India is one of the highest in the world, with about 32 of every 100,000 girls killing themselves. With tens of thousands of teenage girls receiving the HPV vaccine, it would have been unusual if none of them went on to kill themselves (Berkley 2013).

The Supreme Court ruling discussed at the beginning of this paper prompted a raft of reform measures aimed at strengthening protections for Indian clinical trial participants. These include: (i) a more rigorous ‘three tier’ committee system for screening clinical trial protocols at the DCGI; (ii) three new criteria for evaluating clinical trials, namely (a) assessment of risk versus benefit to the patients, (b) innovation vis-à-vis existing therapeutic options and (c) unmet medical need in the country; (iii) audio-visual recordings of the informed consent process, and: (iv) the mandatory registration of Indian Ethical Review Committees (Choudhury and Ghooi 2013; Goyal 2014).

Most controversial were further rules relating to compensation for clinical trial-related injuries or death. Some measures, which aim to strengthen procedural oversight so that incidents are investigated properly and compensation paid if appropriate, are in line with international approaches. Yet some of the new criteria for compensation depart radically from the regimes

in other countries. For example, one provision states that ‘In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required’ (Ghooi 2013). This would seem to apply regardless of whether the trial itself had caused a medical problem. Another rule states simply that subjects shall be eligible for compensation for ‘use of placebo in a placebo-controlled trial.’ Entitlement to compensation was also established for failure of an investigational product to provide the intended therapeutic effect.

These changes caused serious concerns among trial sponsors about legal and financial risks and led to an exodus of clinical trials from India. The numbers of clinical trials approved by CDSCO fell from 500 in 2010 to just 107 in 2013. Sponsors and CROs shifted their activities to ‘rival’ countries with more favourable regulatory systems. Alarmed by the impact on its clinical trial industry, the Indian government watered down some of the reform measures for compensation and for audio-visual recording of consent procedures. The CEO of Quintiles, a major global CRO, said in April 2016 that its concerns over open-ended responsibility to compensate trial participants (or their families) for all adverse events and deaths have been ‘set at rest’ (Das & John, 2016). Furthermore, in January 2015, and in line with the Modi government’s pro-business strategy, the Ministry of Health has proposed ‘pre-submission meetings’ between drug regulators and stakeholders in order to increase efficiency and speed up approval times (Nair 2015). It remains to be seen whether the efforts to entice business back to India can be made compatible with the enhanced protections for Indian trial participants that is – rightly – demanded by advocacy groups in civil society, Parliament, and the Supreme Court.

Violence: structural and symbolic

Violence enters into discussions of the ethics of clinical trials when considering the possible risks of sick or otherwise vulnerable people being coerced into taking part. Well-known

historical examples reveal that participants often had little or no choice – most obviously, those in prisons of one kind or another. The ethical codes that I describe below therefore attempt to ensure that individuals who are approached to join a clinical trial are in a position to make a voluntary choice about whether or not to be involved. This principle has become institutionalised as informed consent: the provision of adequate information, usually in written form, but often supplemented orally, to ensure that the choices made by potential participants are not based on false claims about either the costs or the benefits of taking part. Those running trials are expected to provide this information in a form that allows for the trial's implications to be easily understood.

As it stands, this 'ethical codes' approach is vulnerable to the criticism that it fails to locate the relationships between researchers and researched in the wider social, political and economic contexts within which such interactions take place. In other words, such an approach is framed around the idea that those conducting the research, and those being asked to participate in it, exist in a free-floating world of the liberal ideal 'individual'. In this perspective, the problems associated with clinical trial management are about the ethics of individual motivation and behaviour of those requesting informed consent. The solutions tend to be sought in Standard Operating Procedures (SOPs), protocols and documentation. Morality, not politics, is the focus.

With respect to clinical trials there are two main kinds of critique of this position. The first identifies within clinical trials 'structural violence', in non-Marxist and Marxist versions. I take Jill Fisher as the main proponent of a non-Marxist position and Kaushik Sunder Rajan as representative of an explicitly Marxist position. The second critique, which is less well-developed in this field, considers 'symbolic violence', starting from discussions by Pierre Bourdieu.

Structural Violence: Non-Marxist Approaches

Paul Farmer defines structural violence in terms of ‘social arrangements that put individuals and populations in harm’s way’ that are ‘embedded in the political and economic organization of our social world; they are violent because they cause injury to people’.

Individual agency is not the issue. ‘Structural violence is visited upon all those whose social status denies them access to the fruits of scientific and social progress’ (Farmer 2001: 79), drawing on his experience as both a public health doctor and an anthropologist in Haiti (see, for example, Das et al. 2009; Farmer 1996; Farmer 2001; Farmer 2004; Farmer 2005). The term ‘structural violence’ has a pedigree at least as far back as the work of Johan Galtung (1969) and has links to the work of liberation theologians (Farmer 2004: 307). Victims become so by virtue of their location in social and geographical terms, as members of minority groups or those marginalised or excluded from reaching their full potential because, for example, of their race, class, gender, ethnicity, religious group membership or sexual orientation.

In public health the term provides a call to action over the inequalities that can be observed in epidemiological data: if mortality or morbidity rates are higher in some populations than in others, then these differences can be ascribed to the social structures which work themselves out ‘behind the scenes’.

Jill Fisher uses the concept of structural violence when she argues that ‘informed consent’ in clinical trials rests on unexamined notions of the dyad of researcher-researched, understood as free-floating individuals. ‘The influences of larger social, cultural, economic and/or political realities are almost extraneous within this rubric’ (Fisher 2013: 356). Because ‘the threat or risk of harm stemming from a society rife with inequalities acts as a source of structural coercion for individuals,’ (Fisher 2013: 363-4) she argues for attention to be paid to the ‘lived experiences of research participants’ (Fisher 2013: 356). Even in the best cases, amongst a well-informed population, ‘the process of informed consent in research often nonetheless fails

to achieve its purported ends' (Fisher 2013: 369) because potential participants are enmeshed in webs of structural violence that they carry with them into the clinic or the laboratory. The inadequacies of informed consent are even more likely to be the case where inequalities are steeper, potential participants are poorer, and where they have little access to alternative, affordable, and available health care options. In such circumstances – typical of India – 'informed consent' may act more to protect the researchers from claims for damage incurred during the trial, than to protect the human rights of the trial participants.

Structural Violence: Marxist Approaches

Kaushik Sunder Rajan takes a Marxist view of structural violence, linking the structural violence involved in clinical trials directly to the production of value in capitalist societies. Appeals to the moral or ethical probity of individual researchers are inadequate:

Even if all clinical trials conducted in India or other Third World countries adhered to the letter of the law and the spirit of ethical codes, the very structure of this network [of economic and social relations] would remain one of exploitation (Rajan 2007: 67).

More recently he has analysed 'bio-capital' starting, as Marx does, with value. Rajan suggests that the various crises facing global pharmaceutical economies affect research-and-development based pharmaceutical companies and also the Indian generics drugs industry as they attempt to realise value from the bodies of patients (Rajan 2012: 321). For Rajan, the structure behind structural violence is a capitalist one, one that is recurrently in crisis. The economy of manufacturing and sale of therapeutic molecules depends on an economy of research and development (the current need, for example, to abandon the search for 'blockbuster' drugs and to orient towards personalised medicines). These two economies link to the economy of clinical trials, more and more autonomous, that creates new forms of labour amongst experimental subjects (usually male) as well as among employees (usually female) of

contract research organisations. These three economies link to an economy of health, that is, to the appropriation of health by capital (Rajan 2012: 335-37). In this context he acknowledges the difficulty of arguing ‘for therapeutic access to essential medicines for those who need it while critiquing economies of therapeutic excess and saturation’ (Rajan 2012: 337). The moral critique Rajan implies is that access to people’s bodies for the necessary testing of new or altered drugs is acceptable if and only if it does not involve the bodies of ‘previously marginalized or dispossessed ... subject populations for medical research’ (Rajan 2012: 336)

The term ‘structural violence’ is obviously attractive, since it offers the possibility of thinking about how ‘poverty, hunger, subordination, and social exclusion’ (Farmer 2001: 79) can be included within the term of violence. But those who adopt the perspective of structural violence have been cogently criticised. The term is too general, and it is hard to adapt its use to cover the variety of ‘forms of injustice, their intersections, and the ways in which they are compounded’ (Winter 2012): 195). Its broad-brush approach puts all kinds of constraints into a single category. It is unclear over whether such violence is hidden or visible, and it provides for little more than the use of ‘weapons of the weak’ to challenge it (Scott 1985). Outside the field of a politicised public health, the concept of structural violence has fallen into disuse. The concept’s moral tone can seem to implicate all those who benefit from the status quo and do not act to mitigate its effects on those who are victims of it (Gupta 2012) (Bourgois and Scheper-Hughes 2004; Wacquant 2004). It also draws attention away from the visible physical violence suffered by those who are affected by various kinds of structurally-based damage (Bourgois and Scheper-Hughes 2004).

Thus, particularly in the form in which it has been used by Rajan, it allows too little scope for collective social action to transform those relationships. Can the work of Bourdieu provide a more fruitful approach?

Symbolic violence

For Pierre Bourdieu, symbolic violence is at work when the most powerful groups in any society naturalise their domination. A given social order reproduces itself through processes of misrecognition, ‘the representations of legitimacy [that make possible] the exercise of power’ (Bourdieu and Passeron 1977: 5). Bourdieu effects a conceptual shift ‘from ideology to symbolic violence’ (Wacquant 2013: 278). Misrecognition (*méconnaissance*) is neither a passive process, nor necessarily the result of conscious efforts to hide what is going on. Rather, it is the outcome of multi-level struggles which frame how economic capital is linked to other kinds of capital – symbolic, cultural, and social – and the fields within which these struggles take place. Misrecognition ‘embodies a set of active social processes that anchor taken-for-granted assumptions into the realm of social life and, crucially, that ... are born in the midst of culture’ (Navarro 2006: 19).

What Bourdieu’s approach does is to focus on the social fields in which domination takes place and where it can be contested. It thus provides for spaces in which conflicts appear to set the dominated against the dominant: they are

internecine battles pitting the different sectors of the field of power, that is, different fractions of a putative ruling class whose imperium is rendered both more opaque and more impregnable by the growing intricacy and contradictions internal to the mesh of domination (Wacquant 2013: 278).

This shift matters both theoretically and practically. The analyses of structural violence tend to have an air of fatalism about them: structures are powerful, and responses to them can be little more than token ones. If one form of structural violence – such as social marginalisation – is overcome, or reduced, another is sure to take its place. By contrast, Bourdieu’s approach allows much more for the kinds of struggles that have been taking place in India. Different actors

relating to the field of the clinical trial have come publicly into conflict in real and significant ways, as the opening story of the PATH study makes clear. Misrepresentations can be challenged. Practical proposals can have visible effects. For example, the existing lack of common ground between CRO staff and marginalised participants in India has often been commented on (Srinivasan 2009), and this may make it more likely that trial participants may misperceive their participation as better treatment. It may be possible to enhance understanding if explanations are given to groups as well as to individuals, and if innovative visual aids are used (Sastry et al. 2004), though this finding has been challenged (Sarkar et al. 2010). But some trial participants are only too aware of both their relatively powerless position and the symbolic violence through which they have been persuaded to take part in a trial:

“Of course I'm angry. I've been angry ever since I found out," Mr Shrivastave said. "But what can I do? We are poor people. If I had money I would have filed a case against them straight away, but we don't have money. If I'd known it was a drug trial I never would have agreed. How can I ever trust them again? These people should do trials on their own families, not poor people like me.” (Lakhani 2011)

This awareness does not stand on its own: within India there are civil society organisations prepared to channel it into action, and powerful institutions at the helm of Indian society – the Supreme Court and Parliament, in this case – prepared to go into battle. Following Bourdieu, then, and considering symbolic violence as a set of misrepresentations, we can situate the field of clinical trials as a site for inter- and intra-elite contestations, and understand better the strong civil society, parliamentary and judicial responses to perceived infractions of the human rights of trial participants after 2010. But the Indian contestations do not occur in a vacuum, but are located in a field set by the particular form that global bio-medicine has taken, especially in the past 20 years – but also drawing on a much longer history of conflict and negotiation over ethics and trial procedures.

Conclusion

The issues highlighted by these contestations are several. There are still considerable opportunities for trial participants to be recruited in ways that – despite the researchers following the rule-book – can involve playing on their vulnerabilities, leaving them ill-informed, and without protection if anything goes wrong. Such challenges are not restricted to trials carried out as part of international collaborations, though such studies may be less likely to be drafted in ways that are compatible with ideas of national benefit (e.g. post-trial access to drugs). Yet it is clear that, despite the pressures that were brought to bear by the global pharmaceutical and clinical trial assemblage, India's vibrant civil, political and judicial society has managed to establish protections for trial participants that did not exist before 2012.

These changes suggest that the dichotomous approaches of Farmer and Rajan – essentially positing structural forces that are unchanging and hard to affect, and that determine and require structural violence – are not nuanced enough. Bourdieu's focus on symbolic violence, the ability of people to misrepresent their subjugation and embrace it, but also – often with the help of others – to see through this misrepresentation, as a result of intra- and inter-elite conflicts, is much more helpful. Such an approach makes political effort potentially the basis for shifts, to allow new social forms to come into being, even if the process is slow and fraught with the possibility of sliding backwards. In policy terms, this suggests that state regulation is not enough: to give meaning to the rules needs civil society organisations with a watching brief, able to raise concerns and to alert the regulators – directly or through the media – of abuses. Ethical review committees cannot play this role on their own, nor can international monitors. The ability to think differently about 'the trial' and what it might mean to those who might take part in it, is a crucial outcome of struggle.

In sum, the new situation requires political action to empower those urging more concern for ethical considerations to be taken seriously, and better regulatory frameworks to monitor the

relationships within which trials are conducted. The struggle to work out how best to mitigate the remaining ‘symbolic violence’ is worthwhile, even if how this might be done remains unclear as yet. In addition – and here, structural violence is helpful – the surrounding context of inequality and systematic marginalisation means that removing all forms of subtle, hidden or visible coercion is highly unlikely. The effort has only just started: and it may not last. We cannot be sanguine about the outcome.

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¹ <http://www.path.org/news/press-room/601/>

² See <http://www.nhs.uk/Conditions/Clinical-trials/Pages/Phasesoftrials.aspx>, accessed 13 March 2014, for a simple introduction to the topic.

³ One exception is where large donor agencies such as the Gates Foundation have intervened, for example with respect to vaccine development